#### PATENT

Applicant: Thompson et al. Serial No.: 10/719.727

Filing Date: November 20, 2003
Title: Assembly For Creating
Compound Curves in Distal
Catheter Regions

Group Art Unit: 3767
Examiner: Anderson

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Mail Stop Petition

## PETITION UNDER 37 C.F.R. §§ 1.181 AND 1.104(C)(2)

Sir:

Applicant hereby petitions the Director to instruct the Examiner to issue an action, i.e., a supplemental Office Action or a supplemental Advisory Action, which presents the rejections in a manner that complies with 37 C.F.R. § 1.104(c)(2).

#### Statement of Facts

As discussed in greater detail below, the Examiner has thus far refused to explain how the claims are being read onto the disclosure of U.S. Patent No. 4,940,062 to Hampton ("the Hampton patent") in a manner that complies with 37 C.F.R. § 1.104(c)(2).

Independent claim 8 and dependent claims 9-12 and 15-17 were initially rejected under 35 U.S.C. § 102 as being anticipated by the Hampton patent in the Office Action dated July 26, 2007 ("the Office Action"). The Office Action provided the following "explanation" of the rejection:

With regard to claims 8-12 and 15-17 Hampton discloses (figures 1-12) a catheter steering device, comprising: a main body portion defining a proximal end and a distal end and including a malleable portion between the proximal and distal ends; a deflectable portion associated with the distal end of the main body portion and deflectable relative to the main body portion; and at least one operative element carried by the deflectable portion.

[Office Action at page 2.] The "explanation" was, in fact, nothing more than a reference to every single figure in the Hampton patent and a verbatim restatement of independent claim 8

Applicant made a good faith effort to respond to the Office Action in the November 5, 2007 Amendment. In addition to amendments to various claims, the addition of claims 18-25, and arguments that were based on applicant's best guess as to how the Hampton patent was being applied, applicant requested that any subsequent Office Action explain how the Hampton reference was being applied in a manner that complies with 37 C.F.R. § 1.104(c)(2):

Applicant notes that the discussion of the rejection on page 2 of the Office Action failed to provide any indication whatsoever as to which portions of the Hampton device purportedly correspond to the elements of the claimed inventions. The discussion is, instead, nothing more than a listing of the elements set forth in independent claim 8. Applicant hereby requests that any subsequent Office Action link the elements recited in each of the claims to the elements in the cited reference(s) by Figure numbers, reference numbers, and citations to column and line numbers. [See 37 C.F.R. § 1.104(c)(2) and MPEP § 707.]

[November 5, 2007 Amendment at page 6.]

Independent claim 8 and dependent claims 9-12, 15-17, 19 and 20 were subsequently rejected under 35 U.S.C. § 102 as being anticipated by the Hampton patent in the January 24, 2008 Final Office Action ("the Final Office Action"). On pages 2 and 3, the Final Office Action stated:

With regard to claims 8, Hampton discloses (figures 1-12) a device, comprising: a main body portion (10) defining a proximal end and a distal end and including a malleable portion fixedly positioned between the proximal and distal ends (column 3, lines 11-39); a deflectable portion (13) extending distally from the distal end of the main body portion and deflectable relative to the main body portion; a steering mechanism (15, 18, 14, 24), operably connected to the deflectable portion, that bends the

<u>deflectable portion relative to the main body portion;</u> and at least one operative element (17, 18,47) carried by the deflectable portion.

[Emphasis in original.] The Final Office Action did not identify which element in the Hampton device purportedly corresponds to the claimed "malleable portion" of the "main body portion" and, instead, simply referred to column 3, lines 11-39 of the Hampton patent. This portion of the Hampton patent makes reference to thirteen (13) numbered elements, i.e., elements 10, 11, 12, 13, 14, 15, 16, 17, 18, 20, 21, 22 and 23. Given this shortcoming, applicant's response to the Final Office Action requested that the next action identify, by reference numeral(s), which portion of the Hampton device corresponds to the claimed "malleable portion." [March 19, 2008 Response at page 4.]

Independent claim 21 and dependent claims 22-25 were rejected in the Final Office Action under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Hampton patent and U.S. Patent No. 4,848,352 to Pohndorf. On page 5, the Final Office Action stated:

With regard to claims 21, Hampton and Pohndorf disclose (figures 1-12 and column 3, lines 11-39) a catheter, comprising: a tubular catheter body (10) including a tubular malleable portion (13) and a distal portion that is distal of the tubular malleable portion; a steering spring mounted within the tubular distal portion (figure 6);at least one steering wire (14, 18) that extends through the tubular malleable portion and is connected to the steering spring; and at least one electrode carried by the distal portion of the tubular catheter body.

The Final Office Action did not identify which elements in the Hampton device purportedly correspond to (1) the claimed "distal portion" of the "tubular catheter body" that is "distal of the tubular malleable portion" and (2) the claimed "steering spring" that is mounted within "the tubular distal portion" of the "tubular catheter body." Although the Final Office Action made reference to Figure 6 with respect to the claimed "steering spring," Figure 6 includes a plethora of elements, many of which are identically shown in Figure 1. Given these shortcomings, applicant's response to the Final Office Action requested that the next action identify, by reference numeral(s), which portion of the Hampton device corresponds to (1) the claimed "distal portion" of the "tubular catheter body" that is "distal of the tubular malleable portion" and (2) the claimed "steering spring." [March 19, 2008 Response at pages 8-9.]

The April 15, 2008 Advisory Action (the "Advisory Action") stated that, "[i]n response to applicant's argument that the structural elements are not labeled in the previous Office Action or found in the cited reference, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art." The Advisory Action did not, however, indicate which aspects of independent claims 8 and 21 are "recitations of intended use" that need not be linked to a corresponding aspect of a prior art device.

The Advisory Action also indicated that "[t]he next Office Action will provide a more detailed comparison of the numerous claimed structural elements and the prior art structural elements as requested." In other words, instead of simply using the Advisory Action to address the shortcomings associated with the Final Office Action, the Examiner indicated that the rejections would not be explained until applicant filed a Request for Continued Examination.

### Discussion

The standard for explanations of rejections under 35 U.S.C. §§ 102 and 103 is set forth in 37 C.F.R. § 1.104(c)(2):

When a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable. The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified.

[Emphasis added.] The Final Office Action failed to meet this standard.

The Hampton patent discloses at least three different devices. A guidewire is illustrated in Figures 1-4, a dilation catheter with the guidewire from Figures 1-4 is illustrated in Figures 5-11, and the tip of an alternative guidewire is illustrated in Figure 12. [Column 2, line 47 to column 3, line 7.] The Office Action repeatedly referred to Figures 1-12, which together illustrate three different devices, and referred to Figure 6 in the context of a rejection that appears to be based on the device illustrated in Figures 1-

4. Applicant respectfully submits, therefore, that this aspect of the Final Office Action is anything but "designated as nearly as practicable" or "clearly explained."

With respect to independent claim 8 in particular, the Final Office Action failed to designate which element in the Hampton device purportedly corresponds to the claimed "malleable portion" of the "main body portion" and, instead, simply referred to a portion of the Hampton patent that makes reference to thirteen (13) numbered elements, i.e., elements 10, 11, 12, 13, 14, 15, 16, 17, 18, 20, 21, 22 and 23. Clearly, it would have been practicable to identify one (or more if that was the case) of these elements in the Final Office Action. It should also be noted that the particular aspect of claim 8 at issue here, i.e., the "malleable portion fixedly positioned between the proximal and distal ends" of the main body portion, is not a "recitation of the intended use."

Turning to independent claim 21, the Final Office Action failed to designate which element in the Hampton device purportedly corresponds to the claimed "distal portion" of the "tubular catheter body" that is "distal of the tubular malleable portion." Given the that Final Office Action was able to designate that the guidewire 10 and coil 13 respectively correspond to the claimed "tubular catheter body" and "tubular malleable portion," it certainly should have been practicable for the Final Office Action to designate which portion of the Hampton device is the "distal portion" of the "tubular catheter body" that is "distal of the tubular malleable portion." It should also be noted that the particular aspect of claim 21 at issue here, i.e., the "distal portion" of the "tubular catheter body" that is "distal of the tubular malleable portion." is not a "recitation of the intended use."

The Final Office Action also failed to clearly designate which element in the Hampton device purportedly corresponds to the claimed "steering spring" that is mounted within "the tubular distal portion" of the "tubular catheter body" and, instead, simply referred to Figure 6 with respect to the claimed "steering spring." Figure 6 includes a plethora of elements, many of which are identically shown in Figure 1, and there is nothing that would have prevented the Examiner from identifying a particular element in Figure 6. It should also be noted that the particular aspect of claim 21 at issue here, i.e., the "steering spring" that is mounted within "the tubular distal portion" of the "tubular catheter body," is not a "recitation of the intended use."

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As illustrated above, the Final Office Action did not present the rejections under 35 U.S.C. §§ 102 and 103 in a manner that complies with 37 C.F.R. § 1.104(c)(2) because the particular portions of the Hampton patent that were relied upon were not designated as nearly as practicable, and the pertinence of the Hampton patent was not

clearly explained.

Request for Relief

Applicant hereby requests that the Director instruct the Examiner to issue an action, i.e., a supplemental Office Action or a supplemental Advisory Action, which presents the rejections under 35 U.S.C. § 102 and 103 in a manner that complies with 37

C.F.R. § 1.104(c)(2).

Fees/Extension of Time

A credit card charge authorization in the amount of \$130 is accompanying the filing of this paper. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638.

Should an extension of time be required for a decision on this Petition, applicant respectfully requests that this paper be considered a petition therefor and authorizes the Commission to charge the appropriate fee to Deposit Account No. 50-0638.

Respectfully submitted.

April 21, 2008

Date

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